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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,202	03/05/2002	Avinash Govind Thombre	PC10833ARTB	6366

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/091,202	THOMBRE ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-27,30-38 and 40-46* is/are pending in the application.

4a) Of the above claim(s) *11,12,16-18,41 and 43-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,10,13-15,19-27,30-38,40 and 42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/13/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement filed 3/13/03, Supplemental Information Disclosure Statement filed 11/21/03, Amendment and Extension of Time filed 01/05/04.

Election/Restrictions

Applicant's election without traverse of species (d), artificial beef in paper filed 01/05/04 is acknowledged. However, applicant traversed the restriction with respect to claim 19. The argument is persuasive, and thus, claim 19 and yeast (species b) are now subject to being rejoined.

Claims 11, 12, 16-18, 41 and 43-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in paper filed 01/05/04.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13 and 14 recite the limitation "composition of claim 1 wherein the palatability improving agent is yeast" in lines 1-2. There is insufficient antecedent basis

for this limitation in the claim. Claim 1 defines the palatability improving agent is selected from the group of artificial egg, artificial beef, artificial poultry, artificial fish, dairy based palatability improving agent and natural herbs and spices, or a mixture thereof. Yeast is not in the Markush group defined for the palatability-improving agent. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 10, 13-15, 19-21, 24-27, 30, 31, 33-35 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Fruthaler et al. USPN 4,681,758.

Fruthaler discloses a shaped, flavored articles for oral administer to animal comprising 5-50% protein-containing material (palatability improving agent), medicament, flavoring agent, and polymeric material (carrier) (column 2, lines 11-50). The protein-containing materials can be derived from plant sources, nominal sources or unicellular organism (yeast) (column 2, lines 53-69). Fruthaler further discloses the protein-containing materials have a particularly attractive beefy aroma and color appearance (column 3, lines 1-2, and lines 58-68).

Claims 1, 13, 14, 19-21, 24-27 and 30-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Eichelburg USPN 4,118,512.

In the case that applicant alleges that the palatability improving agent is yeast, the examiner relies on Eichelburg for the following rejection.

Eichelburg teaches an orally administered composition for improving palatability comprising combination of yeast hydrolyzate and medicament (column 3, lines 50-55). The medicament is selected from a variety of medicaments, including analgesics (column 7, lines 38-40). The yeast hydrolyzate is used in an amount sufficient to enhance the palatability, *e.g.*, from about 0.5% to about 99% (column 9, lines 28-43). The composition further comprises binder, including starch, gum, or carboxymethyl cellulose (column 9, lines 44-57). Eichelburg also teach the composition having moisture content (water content) from about 5% to about 12% (column 7, lines 28-33).

Claims 1, 9, 10, 13-15 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Jans et al. USPN 5,824,336.

Jans discloses a chewable tablet (palatable) for companion animals comprising active agent, binder, filler, yeast in an amount of from 40-70%, and flavoring agent in an amount of from 0.001 to 0.5% (column 2, lines 62 through column 3, lines 1-4). Example 2 discloses flavoring agent is meat flavor. The tablet has hardness strength of 100 Newton (~10.19 kp), (column 3, lines 32-35).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 9, 10, 13-15, 19-27, 30-37, 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichelburg, in view of Likarova USPN 5,224,989 and Evans et al. US 6,506,785.

Eichelburg is relied upon for the reason stated above. Eichelburg is silent as to the teaching of tablet, capsule, pill, cachet, troche, or chewable tablet in claims 22, 23, 36, and 37. Nonetheless, Eichelburg teaches orally administered animal medicament in the wafer, sphere, cube, or other three dimensional shape (column 8, lines 16-32). Therefore, obtaining an oral tablet dosage form would have been obvious within the skilled artisan.

Regarding claims 15 and 42, Eichelburg does not teach the palatability-improving agent is artificial meat.

Likarova teaches a film-forming composition suitable for veterinary medicine, including tablet, pills, granules, or pellets; the film-forming comprises artificial meat or milk flavor, or some other attractants and lurants to make the drug or medicine more tasteful for animal (column 5, lines 31-35). Thus, it would have been obvious for one of ordinary skill in the art to modify Eichelburg's oral animal medicine composition using the film-forming having attractant flavors in view of the teachings of Likarova to obtain

the claimed invention, because the references teach the advantageous results and the desired to have an improve taste composition suitable for animal.

Likarova teaches ibuprofen tablets having artificial flavor coated to mask the taste of the drug (columns 4-5).

Evans teaches a composition for oral administration to mammal comprising carprofen as an analgesic and/or anti-inflammatory agent (see abstract, column 6, lines 65 through column 8, lines 1-31). The composition can be formulated in solid dosage form for palatable oral administration (column 29, lines 1-20). Thus, it would have been obvious for one of ordinary skill in the art to optimize the palatable dosage form of Eichelburg and Likarova using carprofen as a medicament agent in view of the teaching of Evans with the expectation of providing an improve palatable dosage form comprising medicament suitable for companion animal.

Regarding to claims 2-6, it is the examiner's position that the limitation "wherein the palatability improving agent provides for voluntary acceptance of the palatability improving agent by the companion animal which is greater than or equal to about 50% to about 90%" is inherent, because Eichelburg teaches the use of the same materials to obtain the same result desired by the applicant, *e.g.*, an orally-administered medicament having improve palatability suitable for companion animal, including dog and cat.

Claims 1-6, 9, 10, 13-15, 19-27, 30-38 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichelburg, in view of Jans et al. USPN 5,824,336.

Eichelburg is relied upon for the reason stated above. Eichelburg is silent as to the teaching of tablet, capsule, pill, cachet, troche, or chewable tablet, and tablet hardness in claims 22, 23 and 36-38.

Jans teaches a chewable tablet (palatable) for companion animals comprising active agent, binder, filler, yeast, and meat flavor (column 1, lines 53 through column 2, lines 1-67; and example 2). The tablet has hardness strength of 100 Newton (~10.19 kp), (column 3, lines 32-35). Thus, it would have been obvious for one of ordinary skill in this art to combine Eichelburg's oral animal medicine composition in view of the teachings of Jans with the expectation of at least similar result, because the references teach the advantageous results in the use of similar ingredients to obtain an improved palatability composition for companion animals.

Response to Arguments

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

Applicant argues that Likarova discloses compositions with palatability agents as films, not mixed with the active ingredient. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The examiner has not been able to determine the criticality of mixing the palatability agent with the active ingredient, since the palatable composition of Likarova is also exhibit similar result desired by the applicant, namely, veterinary medicine that is tasteful for treated animal.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 03/13/03 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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SUPERVISORY PATENT EXAMINER
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